REMARKS

Reconsideration and removal of the grounds for rejection are respectfully requested. Claims 1-6 were in the application, claims 1-6 have been cancelled and new claims 7-11 substituted therefore.

New claim 7 has been amended for clarity and to conform more closely to U.S. claim formatting requirements. Claim 7 clarifies the relationship between the bone piercing element 2 shaped as a hollow needle, which is fixed within

the prehension body 20, having a first portion forming a hollow penetrating body (24), and an insertion end projecting forward from the prehension body 20, the insertion end having a closed spreading tip 22 [para. 0018] and adjacent lateral openings 21.[para. 0020] The prehension body has a housing L with a bottom support surface, which receives the hollow perforating rod 24 [para. 0023,

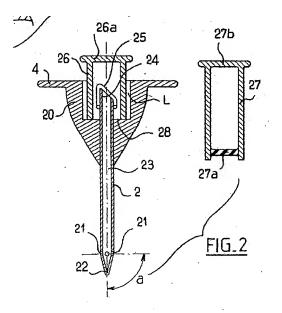


Fig. 2] A capsule 27 is received within the housing, until it engages the support

surface 28. The capsule has a membrane 27a pierced by the rod 24 so as to connect an inner vacuum chamber of the capsule with the aspiration holes for drawing in a sample.[para. 0026-27] No new matter is involved in this amendment.

Claim 6 was objected to for lack of clarity, claim 6 has been replaced by new claim 11 which follows the description in paragraph 0028 of the application, rendering moot the objection.

Claims 1-6 were rejected as being obvious over Garvin, U.S. Patent

6,391,004 in view of Silverman et. al., U.S. patent no. 5,478,328.

In conducting an obviousness analysis, "[a] fact finder should be aware . . . of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning." KSR Int'l Co. v. Teleflex Inc., 127 S.Ct. 1727, 1742, 167 L. Ed. 2d 705 (2007). This is because the genius of invention is often a combination of known elements that in hindsight seems preordained. In re Omeprazole Patent Litig., No. MDL 1291, 490 F. Supp. 2d 381, 2007 U.S. Dist. LEXIS 39670, at 400-01 (S.D.N.Y. May 31, 2007) (citation omitted) (quoting KSR, 127 S.Ct. at 1742); see also Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1138 (Fed. Cir. 1985), Raytheon Co. v. Roper Corp., 724 F.2d 951, 961 (Fed. Cir. 1983) (stating that "virtually every claimed invention is a combination of old elements").

If the prior art teaches away from combining known elements in the manner claimed by the invention at issue, discovering a successful way to combine them is less likely to be obvious. See KSR Int'l, 127 S. Ct. at 1740, 1745.

The applicants' invention is a bone marrow aspiration trocar which differs from prior trocars' in that the present invention uses a spreading tip with a closed end that is fixed in a prehension body that has a housing (L) provided with a bottom surface forming a support surface (28). After the insertion end crosses the skin and perforates the bone to reach the bone outer table, a capsule with a vacuum chamber and having a diaphragm is pressed into the housing (L) until it reaches the support surface (28), with the diaphragm perforated by the perforating rod (24). Once the capsule has been positioned against the support surface, the operator can continue with the penetration action so as to drive the insertion end into a first contact with the marrow, which is detected as soon as the fluid is received. This prevents the needle from being driven in too far, passing through and into the inner bone table, a problem with prior art trocars which required an obstructing rod to prevent plugging the tip

during insertion. These prior trocars failed to give the operator an indication that they were in position, requiring a trial and error approach.

Garvin's device uses a spring loaded and movable needle assembly that is retractable after use. Garvin moreover does not include a housing having a bottom surface forming a support surface for engaging a specimen tube. Once the specimen tube has been inserted inside the outer barrel of Garvin, and the diaphragm is perforated by the rod, there is no structure provided for continuing to insert the tube, nor is there structure for further insertion of the needle end.

Taken as a whole, Garvin would lead one away from the present invention. With reference to column 3, lines 59 to column 4 lines 1-15, the specimen tube (80) has to be inserted inside the outer barrel (50) only until the puncture end (34) of the fluid expelling portion (32) punctures the elastomeric end of the specimen tube (80). (see figure 1). After the user has collected the quantity needed, the specimen tube (80) is removed, another specimen tube can be inserted if multiple samples are needed. When the user has removed the final specimen tube (80), the plunger (40) is inserted into the space between the inner barrel (60) and the outer barrel (50). The user pushes until the annular plunger end (44) urges against the inner barrel (60) which in turn pushes the collet (66) forward so that the collet (66) expands and the holder (30) disengages from the collet (66) and the holder (30) is propelled rearwardly into the tubular body of the inner barrel (60). The needle (10) is then disabled with the needle trapped within the assembly as shown in figure 3.

Thus, in Garvin's device, the specimen tube (80) has to be inserted inside the outer barrel only until the diaphragm has been perforated by the puncture end (32), the specimen tube (80) cannot be moved toward any support surface because the Garvin's device is provided with a needle retractor system actionable by a pushing action.

In fact, after the specimen tube has been inserted until the diaphragm has been perforated, the user cannot perform any further insertion and pushing action but, on the contrary, he has to extract the specimen tube otherwise he will activate the needle retraction system which propel the needle rearwardly inside the assembly.

Thus, a person skilled in the art would not find the present invention obvious in view of Garvin, as Garvin's device cannot be used as a device for bone piercing in order to take marrow bone samples, the needle Garvin's device being suitable only for being inserted through the dermal layer (see column 1, lines 26-30) for collecting blood samples. Also, the outer barrel does not have a bottom surface forming a support surface engaged by the specimen tube.

As Garvin leads one away from the present invention, claims 7-11 are not obvious thereover. Incorporating the disclosure of the various tip designs of Silverman with the disclosure of Garvin does not overcome these deficiencies, as the other features of the claimed invention are not found in Garvin or Silverman, and in fact the design of Garvin requires a movable needle so as to be retractable into a barrel for storage, contrary to the present invention, regardless of the tip design.

Based on the above amendments and remarks, favorable consideration and allowance of the application are respectfully requested. However should the examiner believe that direct contact with the applicant's attorney would advance the prosecution of the application, the examiner is invited to telephone the undersigned at the number given below.

Respectfully submitted,

__/WJS/___
William J. Sapone
Registration No. 32,518
Attorney for Applicant(s)

COLEMAN SUDOL SAPONE, P.C. 714 Colorado Avenue
Bridgeport, Connecticut 06605-1601
Telephone No. (203) 366-3560

Facsimile No. (203) 335-6779